

Appl. No. 09/964,554
Amdt. dated January 21, 2004
Reply to Office action of October 21, 2003

REMARKS/ARGUMENTS

The Official Action dated October 21, 2003 has been carefully considered. It is believed that the claims submitted herewith and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

Claim Objections

The Examiner has objected to claim 16 because it depends on method of treatment claim 1, but yet recites process steps for the isolation of the soyasaponin. The Examiner stated that if a method of treatment claim is intended then the claim has to recite limitations that further narrow the limitations of claim 1. The Applicant wishes to clarify that claim 16 is meant as a method of treatment claim and submits that it is properly dependent on claim 1 as it specifies that the soyasaponin is obtained using the recited method of isolation. As such, claim 16 narrows the limitations of claim 1 by requiring that the soyasaponin be obtained using a specific isolation method. The Applicant submits that no correction of claim 16 is required.

In light of the above, the Applicants request that the Examiner's informality objection to claim 16 be withdrawn.

35 USC §103(a): Obviousness

The Examiner has rejected claims 1, 2, 4, 16 and 21 under 35 USC §103(a) as being obvious in view of Philbrick et al., *J. Am. Soc. Nephrol.*, 10, pp 85A (1999) (hereinafter "Philbrick"). The Examiner's rejection is respectfully traversed.

As asserted by the Examiner, Philbrick discloses reduction in cyst volume for polycystic kidney disease in mice when the affected mice are given an extract containing group B soyasaponins. Philbrick does not delineate between, teach, nor suggest there is a difference in the effectiveness of individual group B sub-types, *inter alia*, B_a B_b, B_b, B_c, B_d or B_e. *A priori*, one is therefore left with the conclusion that administering group B soyasaponins *per se*, is an effective treatment for kidney disease.

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The Applicant wishes to point out that the Examiner's contention that the "Group B soyasaponins as disclosed by Philbrick et al is seen to include soyasaponin B_b in an amount equal to 20% of its total weight" is in error. The 20% number is in reference to the amount of soyasaponins of Group B, in general, that was found in the extract, not to the specific sub-type of group B soyasaponin. In fact, Philbrick is silent about the identity of the sub-types of group B soyasaponins in the extract.

The present invention claims a method which comprises administering "soyasaponin B_b as the sole active ingredient." Indeed, there is no suggestion, teaching, or motivation within Philbrick to select sources of group B soyasaponins which specifically comprise soyasaponin B_b. In fact, there is no teaching in Philbrick that soyasaponin B_b is any more effective than the other identified soyasaponin sub-types. Therefore, the artisan of ordinary skill would not be dissuaded from providing a composition for public use that comprises group B soyasaponins with less than the effective amount of soyasaponin B_b. It is clear, when viewed in light of the present invention, that Philbrick does not even enable the present invention, let alone render obvious the present invention, because Philbrick is silent on the criticality of sub-type B_b for alleviating kidney disease.

The Examiner's attention is drawn to the Federal Court's decision *In re Lalu*, 166 USPQ 1257 (Fed. Cir 1984):

In determining whether a case of *prima facie* obviousness exists, it is necessary to ascertain whether the prior art teachings would appear to be sufficient to one of ordinary skill in the art to suggest making the claimed substitution or other *modification*. (emphasis added)

The modification which Philbrick fails to suggest or to provide motivation for is the isolation, use, and the determination of the relative effectiveness for treating kidney disease of soyasaponin B_b.

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The law is clear when dealing with the specific requirements necessary for the Examiner to sustain a case of obviousness when dealing with prior art teachings juxtaposed to a pending application in the same manner Philbrick is juxtaposed in its teachings to those of the present invention. Again, *In re Lalu*, 1260:

Ultimately our analysis of the obviousness or nonobviousness of appellants' claimed [invention] requires inquiry as to whether there is anything in the [prior art] reference which would suggest the expected properties of the claimed [invention].

There is no teaching, suggestion, or motivation in Philbrick that soyasaponin B_b is the ingredient which must be obtained in order to fabricate the presently claimed invention. According to Philbrick there is no reason to conclude an admixture void of soyasaponin B_b would provide the same result as the present method. It is clear, solely from the court's ruling *In re Lalu* that the Examiner has not met his burden to establish obviousness under 35 USC §103(a).

The Examiner asserts that, even though Philbrick does not teach a specific soyasaponin B to be the active ingredient in the extract, it would have been obvious to a person skilled in the art to treat polycystic disease using soyasaponin B_b since soyasaponin B_b is present in the extract of Philbrick. This argument cannot be sustained.

The Examiner, by his assertion, has acknowledged the differences between the cited prior art and the present invention. The Examiner's rejection is insufficient as a matter of law because it is not supported with any argument, let alone the requisite "facts" required to address the acknowledged difference in the teachings of Philbrick (and its inherent limitations) and the present invention.

The courts have ruled, *In re Freed*, 165 USPQ 570 (CCPA 1970):

As is fundamental, a *prima facie* case of obviousness must be based on facts, *cold hard facts*. (emphasis added)

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Indeed, the court in *In re Freed* reiterates this view at 571, column 1, final ¶:

In this, as in any case, a determination of obviousness must be based on facts and not on *unsupported generalities*. (emphasis added)

Joining in this obloquy with the courts, against unsubstantiated assertions of obviousness under 35 USC §103(a), is the Patent Office's own voice:

When the rejection is not supported by facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1473 (B.P.A.I. 1993).

The Examiner's attention is also drawn to the Federal Court's ruling *In re Dillon*, 13 USPQ 2d 1337 (Fed. Cir. 1989):

There must be some reason, arising in the prior art, to expect that the claimed compounds or compositions will have the properties found by the applicant.

Again, there is nothing in the disclosure of Philbrick to suggest soyasaponin B_b would be the subtype of the group B soyasaponins having the desired activity.

The Examiner's attention is further drawn to the Federal Court's ruling in *In re Sponnoble*, 160 USPQ 237, 243 (CCPA 1969):

A patentable invention may lie in the discovery of the source of a problem [or solution] even though the remedy may be obvious once the source of the problem is identified.

The statute, as well as the findings of the various courts, have put an onerous burden on the Examiner when determining the issue of obviousness. It is clear the knowledge gleaned from the disclosure of the present invention was material in the Examiner making his conclusion of obviousness. Once the Examiner had established the reason for efficacy (i.e. the presence of soyasaponin B_b) it became obvious in the Examiner's view that the present

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invention followed *ad seriatim* from the disclosure of Philbrick. This is exactly what *In re Sponnoble* forbids and which the courts in general distain.

Indeed, nowhere is the Examiner's burden more clearly laid out than in *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984):

A basic issue is whether applied references, alone or in any combination, suggest the claimed Invention as a solution to the specific problem solved. The claimed invention achieved new and unexpected results nowhere suggested in the prior art, and that achievement was overlooked. The initial inquiry should be directed to the vantage point of attacking the problem solved by the invention at the time the invention was made. When prior art itself does not suggest or render obvious the *claimed solution* to that problem, the art involved does not satisfy the criteria of 35 USC § 103 for precluding patentability. (emphasis added)

The Examiner's assertion that Philbrick's disclosure of reduction in cyst volume for polycystic kidney disease in mice when the affected mice are given an extract containing group B soyasaponins renders the present invention obvious, is an erroneous assertion the likes of which the courts have eagerly reversed. Indeed, the Examiner's assertion that, even though Philbrick does not teach a specific soyasaponin B to be the active ingredient in the extract, it would have been obvious to a person skilled in the art to treat polycystic disease using soyasaponin B_b since soyasaponin B_b is present in the extract of Philbrick, cannot be sustained.

With respect to claim 16, which corresponds to claim 1 with the exception that the soyasaponin B_b is isolated using the method described and claimed in the present application, the Examiner has stated that the objections applied to claim 1 also apply in this instance since the method of isolation of a compound is not accorded patentable weight. The Applicants therefore submit that the arguments provided above for the patentability of claim 1, and claim 2 dependent thereon, also apply to claim 16.

In light of the above arguments, the Applicants request that the Examiner's rejection of claims 1, 2, 4, 16 and 21 under 35 USC §103 (a), be withdrawn.

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In view of the foregoing comments and amendments, we respectfully submit that the application is in order for allowance and early indication of that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater detail, he is kindly requested to contact the undersigned by telephone at (416) 957-1683 at his convenience.

Respectfully submitted,

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